UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NOT FOR PUBLICATION

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

MEMORANDUM

- against -

No. 12-CV-763 (ERK)(VVP)

MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*

Defendants.

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KORMAN, J.:

I assume familiarity with the underlying facts and circumstances of this case that are detailed in my memorandum of April 5, 2013. *Tummino v. Hamburg*, --- F. Supp. 2d ----, 2013 WL 1348656 (E.D.N.Y. Apr. 5, 2013). Nevertheless, some introductory words are appropriate. This case involved Plan B and Plan B One-Step, emergency contraceptives that can be taken to reduce the risk of pregnancy after unprotected intercourse. They must, however, be taken as soon as possible after unprotected intercourse. The longer the delay, the less effective they become. The effort to convert these levonorgestrel-based contraceptives from prescription to over-the-counter status has gone on for over twelve years, even though they would be among the safest drugs available to children and adults on any drugstore shelf.

The FDA, responding to unjustified political interference, delayed as long as it possibly could before it took even one incremental step in the process. Ultimately, on December 7, 2011, in response to an application filed by Teva Women's Health ("Teva"), the FDA concluded that Plan B One-Step—the one-pill version of the drug—could be sold over-the-counter and without a prescription or age restriction. On the same day, the FDA was reversed by the Secretary of

Health and Human Services. Some five days later, the FDA rejected a Citizen Petition that sought unrestricted over-the-counter status for Plan B—the original two-pill emergency contraceptive product—and all drugs that are "equivalent" to Plan B. This decision was compelled by the Secretary's reasoning in ordering the FDA to reject Teva's application. Specifically, the Secretary found that information that she deemed essential was not provided by Teva. The Citizen Petition lacked the same information. The Citizen Petition Denial Letter, which came five days after the denial of Teva's Plan B One-Step application, was clearly prompted by the Secretary's action despite the FDA's effort to make it appear that it undertook an independent review of the Citizen Petition. *See Tummino v. Hamburg*, 2013 WL 1348656 at *26.

On April 5, 2013, I issued an order directing the defendants—the Commissioner of Food and Drugs and the Secretary of Health and Human Services—to grant the Citizen Petition filed by the plaintiffs and make levonorgestrel-based emergency contraceptives available over-the-counter and without point-of-sale or age restrictions. Responding to far-fetched concerns voiced in response to the prospect of making the two-pill version available without a prescription, I advised the FDA that if it actually believed there was a significant difference between the one- and two-pill products, it was free to limit the relief on the Citizen Petition to the one-pill product. *Tummino v. Hamburg*, 2013 WL 1348656 at *31.

Passing over the post-judgment proceedings, including the defendants' motion for a stay pending appeal, the defendants now propose to comply with my order by "granting the 2001 Citizen Petition and making Plan B One-Step [] available over-the-counter [] without age or point-of-sale restrictions." Letter from the United States Attorney at 1 (June 10, 2013). They plan to accomplish this by inviting the sponsor of Plan B One-Step, Teva, "to promptly submit a

supplemental new drug application (SNDA) with proposed labeling that would permit [Plan B One-Step] to be sold without a prescription and without age or point-of-sale restrictions." *Id.* Upon receipt of this SNDA, the FDA promises to "approve it without delay." *Id.* Moreover, after it receives and approves Teva's SNDA, it "expects the sponsors" of what it characterizes as generic versions of Plan B One-Step to seek similar over-the-counter status for their one-pill levonorgestrel-based emergency contraceptive products. *Id.*

In their letter, the defendants also state that, "[o]nce the Court confirms that the government's understanding is correct, the government intends to file with the Circuit Court notice that it is voluntarily withdrawing its appeal in this matter." *Id.* The "government's understanding" of my order is not quite correct, although I do not regard any inconsistency with my order as significant. I did not order the defendants to make the brand-name Plan B One-Step available over-the-counter without age or point-of-sale restrictions. Teva did not appeal from the denial of its SNDA seeking this availability, and only the appropriate Court of Appeals would have had jurisdiction to entertain such an appeal. Indeed, in my order denying the defendants' motion for a stay, I expressly rejected the suggestion that I had ordered relief for Teva or that I had the power to do so. If Teva would somehow benefit from the relief sought by the Citizen Petition, it was simply because the relief it sought from the FDA overlapped to a degree with the Citizen Petition. Instead, I ordered the defendants "to make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions." *Tummino v. Hamburg*, 2013 WL 1348656 at *31. Plan B One-Step is one such emergency contraceptive, and granting a new SNDA submitted by Teva and other off-brand manufacturers will have the effect of making it available without a prescription or point-of-sale or age restrictions. This is sufficient to comply with my order.

The plaintiffs argue that the defendants' proposal is insufficient in two ways: first, because it fails to expand access to the currently available (and less expensive) two-pill product, and second, because the defendants do not specify the timeframe within which they intend to comply. Letter from Andrea Costello at 2 (June 12, 2013). The plaintiffs argue that the defendants have failed to establish that any significant difference between the one-pill and two-pill products exists that would justify the continued restriction of the two-pill version. My order, however, is clear that the defendants may limit over-the-counter approval to the one-pill product if they "actually believe[]" that any such difference exists. On the assumption that the Commissioner of Food and Drugs entertains the good-faith belief that the products should be treated differently, the defendants' proposal is sufficient to comply with my order. As for the plaintiffs' second objection, defendants have committed to approving Teva's anticipated SNDA "without delay." If they should fail to do so, the plaintiffs will have a remedy available.

The real concern underlying the plaintiffs' objections is that if the two-pill product is not available to the same extent as the one-pill product, it will somehow operate to increase the cost of the one-pill product by eliminating a competitive alternative. Nevertheless, because off-brand versions of the one-pill product are available, it is at best speculative whether the two-pill product will provide a significantly cheaper alternative. The real problem relating to cost deals with the potential period of marketing exclusivity that the FDA may grant to Teva. Specifically, the defendants' letter states that, "[i]f FDA grants Teva marketing exclusivity, the scope of that exclusivity may affect the labeling that could be approved for generic equivalents of [Plan B One-Step]." Letter from the United States Attorney at 1 (June 10, 2013). The language of the letter obfuscates the true effect of the FDA's grant of marketing exclusivity to Teva. Marketing exclusivity means that no other manufacturer will be permitted to market its products over-the-

counter for three years. This confers a near-monopoly that will only result in making a one-pill emergency contraceptive more expensive and thus less accessible to many poor women.[1] Such exclusivity can only be granted if the FDA determines that studies submitted by Teva in support of its SNDA were "essential" to the FDA's approval of that application. *See* 21 U.S.C. § 355(c)(3)(E)(iv) & 355(j)(5)(F)(iv).

In my order denying the defendants' motion for a stay, I concluded that the plaintiffs were entitled to the relief they sought, even without the actual use study submitted by Teva. Indeed, the 2003 FDA advisory committee formed to consider the first application for over-the-counter access to levonorgestrel-based emergency contraceptives voted by the most overwhelming of margins (27 to 1) to approve it, without the benefit of the actual use study that Teva submitted with its more recent application, and it was only the political interference by the Bush White House that prevented their recommendation from being adopted. *See Tummino v. Torti*, 603 F. Supp. 2d 519, 528 (E.D.N.Y. 2009). Moreover, if the actual use study is essential, it is only because the FDA failed to follow its practice of extrapolating data from older adolescents and also departed from its policy of relying principally on the product label to result in appropriate use. Indeed, as Dr. Andrea Leonard-Segal, Director of the FDA's Division of Nonprescription Clinical Evaluation, wrote in a memorandum reviewed by Secretary Sebelius, "[r]eliance upon the product label to result in appropriate use is consistent with the tenet that the Agency has applied in the past and continues to apply when determining whether or not a product can be over-the-counter. It is an approach consistent with the regulations." Summary Review for Regulatory Action at 28 (Nov. 30, 2011), Case No. 12-cv-763, Doc. No. 83-1.

[1] I use the term "near-monopoly" because the old marketing regime will remain in effect for the two-pill product and off-brand versions of the one-pill product.

In sum, I urge the FDA to carefully consider whether the actual use study is truly essential to its approval of Plan B One-Step for over-the-counter marketing. A three-year grant of marketing exclusivity will only burden poor women. This unfortunate result is difficult to reconcile with the policies underlying the statutory provisions governing marketing exclusivity, which, according to both the FDA and Teva, are intended "to encourage and reward drug manufacturers who devote the time and expense to clinical trials necessary to approve changes to a drug product." Defs.' Resp. to Order to Show Cause at 24, Case No. 12-cv-763, Doc. No. 23; Teva's Proposed Mem. of Law in Resp. to Order to Show Cause at 11, Case No. 12-cv-763, Doc. No. 22-2. Whatever expense Teva incurred, it did not mount a legal challenge to the FDA's denial of its SNDA. Instead, it entered into an agreement with the FDA which allowed it to market Plan B One-Step to women fifteen and over, thus leaving in place burdensome point-of-sale and photo identification requirements. *See Tummino v. Hamburg*, 2013 WL 1921414 at *3-4 (order denying stay pending appeal).

It is only because of the extraordinary efforts by the plaintiffs in pursuing their Citizen Petition that Teva is able to seek approval of an SNDA that will permit it to market its product with no point-of-sale or age restriction. Such approval, if given, will be nothing more than a reward to Teva for playing along with the defendants' efforts to maintain their legally and scientifically unjustified restrictions on the marketing of levonorgestrel-based emergency contraceptives. It is the plaintiffs, rather than Teva, who are responsible for the outcome of this case, and it is they, and the women who benefitted from their efforts, who deserve to be rewarded.

Brooklyn, New York
June 12, 2013

Edward R. Korman
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